91-674

No.

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

Chaves County Home Health Services, Inc., et al

---

v.

Louis W. Sullivan, M.D.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

William A. Dombi
Center for Health Care Law
519 C Street, N.E.
Washington, D.C. 20002
202/547-7424
Counsel of Record

Stanley M. Brand
202/662-9700

Questions Presented

1. Whether the ruling of the Court of Appeals improperly expands the boundaries of statutory construction by the judiciary, as established by the Supreme Court in Chevron, by characterizing the Medicare Act as ambiguous regarding the authority of HHS to process medicare claims onother than an individual basis, while neglecting to analyze the language of the statute at issue. 42 U.S.C. §1395ff.

2. Whether the use of sampling review for post-payment adjudication of Medicare claims violates 42 U.S.C. §1395ff which provides that HHS process all claims of Medicare beneficiaries and health care providers, both initially and on appeal, on an individual basis.

3. Whether the Secretary's implementation of an unwritten post-payment sample review claims adjudication process, in the absence of compliance with the Administrative Procedures Act, 5 U.S.C. § 553, can be retroactively validated through the implementation of HCFA Ruling 86-1 under the Supreme Court's ruling in Bowen v. Georgetown University Hospital.

PARTIES

Petitioners

Chaves County Home Health Services, Inc.
PO Box 237
Roswell, NM 88201

Albuquerque Visiting Nursing Service, Inc.
1200 University N.E.
Albuquerque, NM 87102

Bayonne Visiting Nurse Association, Inc.
325 Broadway
Bayonne, NJ 07002

Respondent

Louis W. Sullivan, M.D., Secretary
Department of Health and Human Services
Room 615-F
200 Independence Avenue, S.W.
Washington, D.C. 20201

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: Page

Statutes and Regulations

UNITED STATES SUPREME COURT
OCTOBER TERM, 1991

Chaves County Home Health Services, Inc.

v.

Louis W. Sullivan, M.D.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Chaves County Home Health Services, Inc., Albuquerque Visiting Nurse Services, Inc., and Bayonne Visiting Nurse Association, Inc. petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The opinion of the Court of Appeals (App., *infra*, 1a-27a) is reported at 931 F2d 914 (D.C. Cir. 1991). The opinion of the District Court is reported at 732 F.Supp 188 (D.D.C. 1989).

JURISDICTION

The judgment of the Court of Appeals was rendered on April 26, 1991. A petition for rehearing and suggestion for rehearing *en banc* was denied on July 26, 1991. (App., *infra* , 1b). Jurisdiction of this Court is invoked pursuant to 28 U.S.C. 1254 (l).

STATUTORY PROVISIONS INVOLVED

The Medicare provisions of the Social Security Act, 42 U.S.C. §1395ff(a), provides in relevant part:

> Determinations of the Secretary
>
> (a) Entitlement to and amount of benefits. The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.
>
> As amended October 21, 1986, P.L. 99-509

Prior to the 1986 amendment, 42 U.S.C. §1395ff(a) provided:

> (a) Entitlement to and amount of benefits. The determination of whether an individual is entitled to benefits under part A or part B and the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him.

STATEMENT OF THE CASE

This case represents a challenge to the Secretary's use of a sample adjudication scheme to review Medicare claims for home health services benefits which had been previously paid by the Medicare program on behalf of individual patients of the petitioners.

Factual background

Petitions are non-profit organizations participating in the Medicare program as providers of home health services, 42 U.S.C. §1395x(o). Medicare makes available to beneficiaries extensive coverage of medically necessary home health services, including skilled nursing, therapy, and home health aide services. 42 U.S.C. §1395x(m).

The initial determination as to whether a claim on behalf of a home health services patient is covered under the Medicare program is delegated to outside government contractors, known as regional home health intermediaries, 42 U.S.C. §1395h. Each claim is processed individually by the intermediaries, and adverse determinations are subject to rights of appeal under 42 U.S.C. §1395ff(b).

None of the petitioners had demonstrated any history of submitting non-covered claims under Medicare as each had been awarded a favorable presumptive status under 42 U.S.C. §1395pp(f) by having a claim denial rate of less than 2.5 percent.

On March 8, 1984, December 28, 1984, and September 20, 1985, Albuquerque VNS, Chaves County, and Bayonne VNA, respectively, were notified that thousands of previously reviewed and paid claims had been readjudicated and denied. However, the intermediaries did not re-review the claims on an individual basis. Instead, the intermediaries substituted a small (as low as 3%) sample review in a post-payment readjudication of the claims which had been previously reviewed at a prepayment stage on an individual, claim-by-claim basis. The results of the sample review were projected to the universe of claims in issue.

Based upon those readjudications, the intermediaries, on behalf of the Secretary, demanded immediate repayment of $138,113.38 from Albuquerque VNS, $46,913.19 from Chaves County, and $1,506,639.00 from Bayonne VNA. The demand for repayment was for an immediate recoupment without postponement to accord the petitioners with any opportunity to seek review through the administrative appeals process.

Albuquerque VNS exemplifies the operation of sample adjudication. There, the intermediary examined only

200 claims of the 2,460 claims which had been previously reviewed on an individual basis and paid. This represented only 8% of the claims submitted between March 5, 1982 and March 25, 1983. Immediately after the coverage denials the Secretary began to withhold direct Medicare payments to collect the alleged overpayment. The VNS initiated administrative appeals, most of which were successful, but could not financially survive and declared bankruptcy on February 2, 1988.

All three petitioners contested the Secretary's authority to deny Medicare coverage through a sample adjudication scheme which supplanted the original determinations which individually found the claims as within Medicare requirements for payment. Petitioners also pursued appeals of the merits of the coverage determinations issued on the sample claims.

While administrative appeals were pending before administrative law judges (ALJ), the Secretary issued HCFA Ruling 86-1 (App., *infra* , 1c-c) which was binding on the ALJs and compelled them to reject jurisdiction over a challenge to the Secretary's use of a sample adjudication scheme. HCFA Ruling 86-1 was issued February 20, 1986.

The ALJ in the Albuquerque VNS case refused to be bound by HCFA Ruling 86-1 and held that the scheme violated numerous provisions of the Medicare Act and regulations. Subsequently, the Appeals Council, 42 CFR §405.724; 20 CFR §404.967, vacated the ALJ's ruling based upon the binding nature of HCFA Ruling 86-1.

The ALJs in the Chaves County and Bayonne VNA cases both ruled that HCFA Ruling 86-1 was binding upon them and that they were without jurisdiction to review its validity.

The administrative appeals process eventually led to the reversal of virtually all claim denials and a corresponding reverse extrapolation of the effect of sample adjudication. However, the appeals process highlighted the practical effect of sample adjudication as follows:

- Claims which had been previously reviewed on an individual basis were, in practical effect, denied through the projection of the sample results.

- Repayment of the projected claims denials was required prior to the completion of the administrative appeals process.

- Where individual claims in the sample did not meet the jurisdictional amount in controversy of $100 under 42 U.S.C. §1395ff(b), there was no right to a hearing despite the fact that the extrapolated effect of sample review incurred a repayment obligation in excess of a $100 amount in controversy. These home health agencies were permanently deprived of thousands of dollars in previously paid claims without a hearing through this element of the sample adjudication scheme.

- The appeals process has yet to be completed on some claims over 5 years after the original denials.

- Rights of appeal available only subsequent to a repayment obligation, combined with the risk of erroneous coverage determinations forced Albuquerque VNS into bankruptcy on February 22, 1988 after 35 years of service within its community.

Proceedings below

On September 29, 1986, litigation was commenced in the United States District Court for the District of Columbia, *Chaves County Home Health Services, Inc., et al* v. *Bowen*, Civil Action No. 86-2691. Ultimately, the district court denied defendant's motion to dismiss for lack of subject matter jurisdiction, denied plaintiff's motion for summary judgment and granted defendant's motion for summary judgment. 732 F.Supp 188 (D.D.C. 1989). The general basis for the district court's ruling was a reliance upon the broad powers of the Secretary to make adjustments in payments pursuant to 42 U.S.C. §§1395g(a); 1395u(a);

1395x(v)(1)(A)(ii), *Chaves County Home Health Services, Inc.*, v. *Sullivan*, 732 F.Supp 188 (D.D.C. 1990).

On appeal to the Court of Appeals for the District of Columbia Circuit, the panel affirmed the district court's rulings on other grounds. 921 F.2d 914 (D.C. Cir. 1991). The Court of Appeals rejected the district court's statutory basis, Id. at 918; App., *infra*, 8a. However, the Court held that the ambiguity of the Medicare Act relative to the Secretary's authority to engage in sample adjudication combined with deference to the Secretary's interpretation under the standard enumerated in *Chevron U.S.A., Inc.* v. *National Resource Defense Council*, 467 U.S. 837 (1984) justified an affirmance of the result.

The Court of Appeal found that "sample adjudication is not, however, a determination that some particular though unidentified claims outside that sample should have been denied; instead it is a monetized estimate of the scope of a provider's overcharges from a sample." Id. at App., *infra*, 15a. The Court suggested that providers could remedy its harm by directly billing beneficiaries who had been previously on notice that their services were noncovered or appeal the sample determination by establishing that all claims in the universe actually satisfied Medicare coverage standards thereby demonstrating the invalidity of the denial projection. Id. at App., *infra*, 15a. No such opportunity exists either practically or within the jurisdiction of an appeals process.

REASONS FOR GRANTING REVIEW

I. *The Court of Appeals Has Created A New Standard Of Statutory Construction In Failing to Analyze the Language of the Statute at Issue.*

Under 42 U.S.C. §1395ff(a), the Medicare Act definitively requires that all determinations regarding coverage of home health services must be rendered by the Secretary on an individualized, claim-by-claim basis. Here, the Court of Appeal's ruling is subject to a fatal flaw: the Court has failed to even reference the statute at issue, let alone analyze its language. As such, the Court's ruling is directly contrary to the well established principles of statutory construction which require that the first step in the analysis is the statutory language itself. *Chevron U.S.A., Inc. v. National Resources Defense Council,* 467 U.S. 837, 843-844, 104 S.Ct. 2778, 2781-2; 81 L.Ed. 2d 694, 703 (1984).

The Court of Appeals' ruling is founded on a single, guiding conclusion that the statute is ambiguous or silent relative to the authority of the Secretary to engage in sample claim adjudication. This finding led to the premature and unnecessary analysis of whether the agency's interpretation of the statute represented a permissible construction or one which is arbitrary and capricious. *Chevron*, supra at 843-84.

While the Court of Appeals found nothing in the statute expressly allows or disallows sample audits, App., *infra*, 5a, court utterly failed to analyze 42 U.S.C. §1395ff(a) which requires that all claims be determined on an individual basis exclusively. Specifically, 42 U.S.C. §1395ff(a) requires the Secretary to issue determinations "of whether an individual is entitled to benefits . . . (emphasis added). It is the clear exclusivity of the *individual* claim determination process which precludes the use of sample adjudication.

The Court of Appeals' failure to even note the statute deemed ambiguous creates a dangerous precedent, at odds with all

decisions of the U. S. Supreme Court establishing the principles of statutory construction. If left undisturbed, this ruling creates a license for the federal court to ignore Congressional mandates, overturn agency interpretations, and substitute its own policy choices under the guise of statutory ambiguity. It is the power of Congress to legislate. Administrative agencies implement legislative acts through regulation. The judiciary is responsible for determining what a law means. *Chevron*, supra at 843 fn 9. The courts should not be allowed to usurp the role of Congress and administrative agencies through the use of unfocused, undefined power to declare a statute ambiguous.

It is crucial that this Court intervene to stem this judicial activism through the reinforcement of its longstanding principles of statutory construction. Here, it is not the statute governing the Secretary's process for Medicare claim determinations that is ambiguous. Rather, it is the ruling of the Court of Appeals that is silent as to the statutory and regulatory basis for its decision.

The Supreme Court's well-settled principles of statutory construction require that:

> When a court reviews an agency's construction of the statute it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the Court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the Court determines Congress has not directly addressed the precise question at issue, the Court does not simply ignore its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Chevron, U.S.A., 467 U.S. at 842-843; 104 S.Ct. at 2781-2; 81 L.Ed. 2d at 702-3. (footnotes omitted)

While debate has raged concerning a proper meaning of the term "ambiguous", *See*, Sunstein, *Law and Administration After Chevron*, 90 Colum. L. Rev. 2071, 2091-2093, there is no dispute that resolution of conflict regarding the meaning of a law must begin with the statutory language itself. *Schreiber v. Burlington Northern, Inc.*, 472 U.S. 1,5; 105 S.Ct. 2485, 2461; 86 L.Ed. 2d 1, 5-6 (1985). "In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291, 108 S.Ct. 1811, 1817; 100 L.Ed. 2d 313, 324 (1988).

The Supreme Court has successfully preserved this principle of statutory construction over the years. Regardless as to whether the Court ultimately accepted or rejected a federal agency's interpretation of the law, the Court has always begun its analysis with the language of the statute to determine Congressional intent and the extent of delegated administrative authority to interpret the law. *See*, e.g., *Rust v. Sullivan*,___U.S.___; 111 S.Ct. 1759 L.Ed. 2d 72(1991)(review of the term "method of family planning" under 42 U.S.C. §300a-6a regarding the limitation of use of federal funding for abortion counseling, referral, and advocacy); *Sullivan v. Everhardt*, ___U. S. ___; 108 S.Ct. 960; 108 L.Ed. 2d 72 (1990) (authority of Secretary to make "proper adjustment or recovery" when he "finds that more or less than the correct amount" of "payment" has been made under 42 U.S.C. §404(a)(1)(A),(B)(1982 ed. Supp. IV)); *Dole v. United Steelworkers of America*, ____U.S.___; 110 S.Ct. 929; 108 L.Ed. 2d 23 (1990)(interpretation of terms "information collection request" and "collection of information" defined as "the obtaining or soliciting of facts by an agency through . . . reporting or recordkeeping requirements" under the Paperwork Reduction Act, 44 U.S.C. §3502); *Sullivan v. Zebley*, ___U.S. ___; 110 S.Ct. 885; 107 L.Ed. 2d 967(1990)(meaning of "comparable severity" of child's disability in relation to adult's disability under 42 U.S.C. §1382(c)(a)(3)).

In fact, the Supreme Court has often turned to dictionary definitions of terms in order to understand their meaning and the potential for ambiguity. *See*, e.g., *Pittston Coal Group v. Sebben*, 488 U.S. 105, 113; 109 S.Ct. 414, 420; 102 L.Ed. 2d 408, 420 (1988), reference to Webster's Ninth Collegiate Dictionary for definition of "criteria"). A law cannot be considered ambiguous without reference to the language at issue.

The Court of Appeals' ruling is utterly devoid of any reference to the statutory provision deemed ambiguous. Instead, the Court of Appeals refers to statutory provisions which it concludes as inapplicable and others which provide authority for the recovery of overpayments, but not the process for determining whether an overpayment has been made. This deficiency in the Court of Appeals' analysis is highlighted in its review of HCFA Ruling 86-1 (App. *infra*, 8a). It was HCFA Ruling 86-1 which the Secretary claimed as the explanation of the authority for the policy on sample adjudication.

The Court of Appeals rejected the Secretary's claimed statutory authority. In finding the cited authority, 42 U.S.C. §1395g(a); 1395u(a); 1395x(v)(1)(A)(ii), governed reasonable cost determinations rather than the issues of coverage determinations presented in Petitioner's claim, the Court concluded that "we do not read these provisions as explicit statutory authorization for sample adjudication or post-payment review of coverage determinations." App. *infra*, 8a. The Secretary has never offered any other statutory basis, ambiguous or otherwise, for the alleged authority to engage in sample adjudication.

The Court of Appeals' difficulty with the issues is due to efforts to locate statutory language which "expressly disallows" sample adjudication. App. *infra*, 5a, 6a. In attempting to find a statutory preclusion for sample adjudication, the Court ignored the single statutory provision which establishes the authority of the Secretary regarding the method and process of coverage claim determinations. 42

U.S.C. §1395ff(a). As discussed below, Section 1395ff(a) is the exclusive method and process for issuance of any determination affecting coverage of home health services under Medicare Part A. Section 1395ff(a) controls the process of determinations by the Secretary, precluding sample adjudication, not by way of explicit exclusion, but by limiting the authority of the Secretary to the issuance of individualized determinations exclusively.

To maintain the integrity of the principles of statutory construction, the Court of Appeals must examine the language of 42 U.S.C. §1395ff(a), apply the plain meaning of that language, analyze the provision in its overall context of the Medicare program, and determine then whether the statute is ambiguous. The Court of Appeals missed the first step, and as a result, stumbled through the remaining components of the process.

The Court of Appeals' method of statutory construction has broad implications within Medicare and well beyond. If a court can proceed to a Chevron step two analysis, *Chevron*, 467 U.S. 837, 843 (1984) without reference to the language of the statutory provision at issue, no act of Congress is sacred. Likewise, the *Chevron* step two analysis provides the vehicle for a court to reject an administrative regulation as unreasonable or arbitrary and capricious thereby further dismissing the intent of Congress and the expertise of the administrative agency. Effectively, the rule of statutory construction devised by the Court of Appeals creates the opportunity for policy making and legislating with the judicial branch.

An application of the method of statutory construction employed by the Court of Appeals to recent cases decided by the Supreme Court highlights the dangers attendant to a standard which does not focus on the statutory language as its starting point.

In *Dole v. United Steelworkers of America*, ___U.S.___; 110 S.Ct. 929; 108 L.Ed. 2d 23 (1990), the Secretary of Labor withdrew a Hazard Communication Standard which

imposed disclosure requirements which were designed to ensure that employees were informed of potential hazards posed by chemicals in the workplace. The Standard had been submitted to the Office of Management and Budget (OMB), for review under the Paperwork Reduction Act of 1980, 44 U.S.C. §3501, *et seq.* OMB disapproved three of the standards based on its determination that the requirements were not necessary to protect employees. The Secretary, despite her disagreement with OMB's assessment, published a notice in the *Federal Register* withdrawing the three standards at issue. The question ultimately presented to the Court was whether OMB had authority under the Paperwork Reduction Act to review and countermand agency regulations mandating disclosure by regulated entities directly to third parties.

As appropriate under existing standards of statutory construction, the Supreme Court turned to the language of the Paperwork Reduction Act to determine the authority of OMB on the issue presented, The Court found that,

> "No provision of the Act expressly declares whether Congress intended the Paperwork Reduction Act to apply to disclosure rules as well as information gather rules." *Id.*, 110 S.Ct. at 934; 108 L.Ed. 2d at 32.

In the absence of explicit inclusion or exclusion of disclosure rules, the Court proceeded to examine the language of the statute itself. 44 U.S.C. §§3502(ii), 3502(4)(1982 ed. Supp. V). A detailed analysis ensued with the Court applying a "common sense" reading standard of such terms as "reporting or recordkeeping requirements", "solicit", "obtain", and "records". 110 S.Ct. at 934; 108 L.Ed. 2d at 33-34. The Court reinforced its interpretation of these terms through consideration of the object and structure of the Act as a whole. 110 S.Ct. at 934; 108 L.Ed. 2d at 34. Ultimately, the Court declined to defer to OMB's interpretation of the Act, as found in federal regulation, based upon its findings "that the statute, as a whole, clearly expresses Congress' intention." 110 S.Ct. at 938; 108 L.Ed. 2d at 38.

If the Court in *United Steelworkers* had ignored the language of the Paperwork Reduction Act following its finding that the Act did not *expressly* apply to disclosure rules, deference to OMB regulations would have likely affirmed OMB's claimed authority to reject agency regulations mandating disclosures by regulated entities to third parties. Under the agency deference standard set out in *Chevron*, 467 U.S. 842-845, the dissent in *United Steelworkers* concludes that the OMB's interpretation is reasonable and therefore valid. 110 S.Ct. at 40 (White dissenting).

As with the Paperwork Reduction Act regarding its application to disclosure rules, no provisions of the Medicare Act "expressly declares" whether sample adjudication is prohibited or permitted. *Chaves*, App. *infra*, 5a. Nonetheless, instead of proceeding to examine the statutory language in 42 U.S.C. §1395ff(a) setting forth the Congressional mandate relative to claim determinations, the Court of Appeals here simply labeled the Medicare Act ambiguous and deferred to the Secretary's policy interpretation, set out in HCFA Ruling 86-1.

Under the Court of Appeals' standard, the Supreme Court ruling in *Sullivan v. Zebley*, ___*U.S.* ___ ; 110 S.Ct. 885; 107 L.Ed. 2d 967 (1990) is equally vulnerable. In Zebley, the Court invalidated regulations which restricted the parameters for review of a claim for child's disability benefits under the Supplemental Security Income Program (SSI) Title XVI of the Social Security Act, as added 86 Stat. 1465, and amended, 42 U.S.C. §1381 *et seq.* (1982 ed. and Supp. V). The Court concluded that the child-disability regulations could not be reconciled with the language of the authorizing statute.

At issue in *Zebley* was the meaning of the phrase "any medically determinable physical or mental impairment of comparable severity" under 42 U.S.C. §1382c(a)(3). The Social Security Act had defined "disability" in reasonable detail relative to individuals over the age of 18. A child under 18 was considered disabled if he/she met the standards developed under the parenthetical phase set out above.

The Secretary implemented §1382c(a)(3) through a series of regulations which establish a five step test of disability for adults and an abbreviated version for children, limiting the analysis to the first three of the five step adult disability test. Under the fourth and fifth steps of the adult test, the Secretary reviewed whether the claimant could perform his/her past work or any other work in the economy, in view of his age, education and work experience. No comparable analysis existed for review of a child's disability.

The Court rejected the regulations through an application of the statutory language to the regulations, finding that limiting the disability determination to a three step test resulted in a standard more severe than that set out in the statute. 110 S.Ct. at 896. The child disability standards were not "comparable" if they acted to exclude individuals who, as adults, could qualify for benefits under the fourth or fifth step of the adult disability test. The Court dismissed the Secretary's contention that a vocational analysis (a component of the fourth and fifth step) is inapplicable to children since they have not worked, finding that a comparable functional analysis could be applied. *Ibid.* Since the child disability analysis was "manifestly contrary to the statute," the Court accorded no deference to the Secretary's interpretation. 110 S.Ct. at 897.

Under the Court of Appeals' standard of statutory construction at issue here, the Supreme Court would have likely found the statute of concern in *Zebley* ambiguous and then deferred to the Secretary's interpretation unless that interpretation was determined arbitrary or capricious. While such conclusion might be considered speculative, a finding of ambiguity in the statute was the basis for the dissenting position that the regulations were valid. 110 S.Ct. at 898 (White dissenting). The statute did not explicitly require that the Secretary consider "nonmedical factors" or "specific consequences that an impairment must or should produce." *Ibid.* However, the Court instead met its responsibility of examining statutory language directly and in its overall context to integrate the reference of "comparable severity"

with the complete elements of a disability determination operative for adult claimants. If the Court of Appeals' standard had been applied, the Court's statutory analysis in *Zebley* would have ended when no specific inclusion of a functional analysis was found.

Here, the Medicare Act never uses the phrase "sample adjudication" or an equivalent within any statutory provision. However, the absence of specific terms on phrases from statutory language does not demonstrate, *per se*, that the statute is ambiguous relative to the authority of an administrative agency. For example, while 42 U.S.C. §1395ff(a) references "determinations" of the Secretary as subject to appeal, the Secretary cannot deny an appeal to an aggrieved claimant simply by labeling an action of the Secretary as a "decision" instead of a "determination." The Court of Appeals' standard for review as to whether a statute is ambiguous completely ignores the language of the statute and the meaning of the words within a statute. Under 42 U.S.C. §1395ff(a), sample adjudication is expressly excluded through the manifestly clear limitation of the Secretary to issue individual determinations exclusively.

To allow the Court of Appeals to maintain a standard of statutory construction which does not begin with the language of the statute and which instead requires that Congress enact the exact words or phrases at issue in the action before the court is a disastrous precedent. Had the Supreme Court in *United Steelworkers* and *Zebley* applied a similar standard, the intent of Congress would not have been honored. Congress cannot be held to a standard of statutory drafting which requires it to use each and every potentially applicable word in the English language to ensure that the legislative intent is followed.

If Congress were to mandate that all paper currency must be printed with green ink, its intent would not be ambiguous simply because it did not specifically state that the currency could not be printed in red, blue, yellow or any other existing color. However, to determine whether Congress would allow for other ink colors to be used in combination with

green, the courts would need to examine the language of the statutory provision to determine whether the plain meaning of the law would allow such interpretation.

Alarmingly absent from the Court of Appeals' analysis is any review of its language of 42 U.S.C. §1395ff, the sole provision of the Medicare Act which establishes the authority of the Secretary to issue claim determinations under Medicare Part A. If the Court of Appeals can adjudge the clarity or ambiguity of Congressional intent without reference to the language of the statute, then no act of Congress is safe from arbitrary judicial rejection.

The dire consequences of the Court of Appeals' approach can also be felt within the administrative agencies. A finding of statutory ambiguity leads to review of an agency policy or regulations under a test of reasonableness. *Chevron*, supra at 843-44. Within this step of the analysis, a court has the opportunity to substitute its own consideration of reasonable policy for that of the administrative agency. Failure to analyze the pertinent statutory language is the equivalent of attempting to determine Congressional intent in a vacuum. The Court of Appeals has failed to adhere to the most basic test of statutory construction: the "starting point is the language of the statute." *Schreiber v. Burlington Northern, Inc.*, 472 U.S. 1,5; 105 S.Ct. 2458, 2461; 86 L.Ed. 2d 1, 5-6 (1985).

II. *The Court of Appeals Ruling Has Broad Ramifications Within the Medicare Program Through Validation of Sample Claims Adjudication which Violates the Rights of Beneficiaries and Providers to Individualized Claims Determinations and Appeal..*

The natural and forseeable effect of sample adjudication in Medicare is fear. The extrapolated effect of a single claim denial in a process of sample adjudication can be thousands of dollars. For home health agencies, operating on "reasonable cost" reimbursement, 42 U.S.C. §1395x(v), there is literally no profit, no margin in Medicare revenue that can be used to offset a monetary recovery occasioned by retroactive claims denials in a sample adjudication system. With most home health agencies relying upon cost-based payments from Medicare and Medicaid (Title XIX of the Social Security Act, 42 U.S.C. §1396 *et seq.*) repayment of an alleged overpayment is nearly impossible. The costs of providing any non-covered care have already been incurred. Recourse to recovery from the patient is generally unavailing as many may not be still alive, let alone with sufficient funds at the time of sample adjudication.

However, this is not a case where providers of home health agencies are screaming foul because they stand to lose money in a government financed health care program. Likewise, it is not an attempt by providers to take advantage of a gigantic health insurance program that cannot afford to pay attention to little details as required in a claim-by-claim adjudication program. Instead, it is a case concerning the integrity of the Medicare program wherein the beneficiaries are guaranteed the right to be treated as individuals, with unique conditions and needs requiring health care services. It is a case involving rights of beneficiaries and providers alike to fair notice and appeals. Most importantly, it is a case which seeks to ensure that the Congressional goal of access to health care for this nation's elderly and disabled is not obstructed by a fear inducing device known as sample adjudication.

To understand the environment of fear created by sample adjudication and its disastrous effect on access to home health services under Medicare, four factors must be understood. First, under Medicare's waiver of liability provision, 42 U.S.C. §1395pp, a retroactive claim denial can shift liability for the cost of services already rendered from Medicare or the beneficiary to the provider of care. Second, historically, the Medicare administration has demonstrated that the risk of an erroneous coverage denial by its fiscal intermediaries is very high. Third, an error in a claim determination by the intermediary is exponentially magnified through a system of sample adjudication. Fourth, the provider of services can only reduce its risk of shifted liablity through restricting access to care for beneficiaries.[1]

This environment of fear and the resulting "chilling effect" on access to care is not mere speculation offered to justify this Court's granting of the petition for writ of certiorari. Rather, it is based upon historical facts which demonstrated that home health agencies and their patients are ready victims to arbitrary claims determinations by the Medicare program.

In the mid-1980's, the Medicare home health benefit was under attack and was at risk of total dismantling. Coverage denials had skyrocketed and home health agencies were providing care, not in accordance with patient needs, but in

---

[1] It must be understood that home health agencies are not challenging sample adjudication to retain Medicare payment for non-covered services. Instead, the challenge is an effort to curtail the magnification of erroneous coverage denials where the Secretary recoups alleged overpayments prior to the opportunity of the home health agencies to reaffirm the actual coverage of the services at issue which had been established at initial prepayment review.

conformity with erroneous and arbitrary coverage determinations by Medicare intermediaries. The program was in shambles.[2]

In order for the organizations to survive and provide some care to home care patients, the home health agencies ran scared from the Medicare program. Their greatest fear was the risk of shifted liability under 42 U.S.C. §1395pp for a retroactive coverage denial which would lead to a reimbursement recovery of Medicare payment for costs already incurred. The appeals process was available, but of little solace since a hearing before an administrative law judge under 42 U.S.C. §1395ff(b) came one to two years after the coverage denial. The only other recourse was to reduce services and access to care for Medicare beneficiaries in an effort to reduce the volume of arbitrary coverage denials. This "chilling effect" was both obvious and forseeable.

On March 17, 1987, a coalition of Medicare beneficiaries, United States Congressmen, and home health agencies filed a nationwide class action lawsuit challenging Medicare's decisionmaking process, *Duggan, et al. v. Bowen*, Civil Action No. 87-383-SS, (D. D.C.). Following a court ruling on one of the claims presented, *Duggan*, 691 F. Supp. 1487 (D.D.C. 1988), the parties proceeded to settlement wherein coverage standards were clarified and re-written. That settlement process continues today with a recently published Notice of Proposed Rulemaking concerning the home health services benefit coverage criteria. 56 Fed. Reg. 49154 (September 27, 1991).

The preamble to that proposed rule sets out the overriding principle of Medicare coverage determinations:

> "A coverage denial may not be made solely on the basis of the reviewer's general inferences about

---

2 *See generally*, GAO Report, No. HRD-90-14BR (January 24, 1990. Subject: Increase Denials of Home Health Claims During 1986 and 1987, CCH Medicare and Medicaid Guide, ¶ 38,386.

> patients with similar diagnoses or on data related to utilization generally, but must be based upon objective clinical evidence regarding the *patient's individual need* for care. Hence, each decision as to whether care is reasonable and necessary, as required by section 1862(a)(1)(A) of the Act, is *unique* in that it hinges upon the condition of a *specific beneficiary*." 56 Fed. Reg. at 49160 (emphasis added).

The use of a sample adjudication process is not simply a "monetized estimate of the scope of a provider's overcharge derived from the sample." *Chaves County*, App., *infra*, 15a. Instead, it is a blatant rejection of Medicare's longstanding principle which recognizes that the health care needs of the Medicare beneficiary and right to coverage depends upon his/her unique and specific condition. While the Court of Appeals recognized the importance and value of this right to an individualized determination at the pre-payment stage, App., *infra*, 6a, it eradicates that right in ruling that sample adjudication can supplant individual coverage determination on post-payment review. The guarantee of individual determinations is thereby rendered meaningless and can only be viewed as a sham.

The Court of Appeals' ruling cannot be considered as one supported by deference to the interpretation of law by an administrative agency. Rather, it is judicial policymaking in full fever. First, the Court ignores the only statutory provision which governs coverage determinations affecting home health services, 42 U.S.C. §1395ff(a). Second, the Court creates out of thin air a distinction between the process of pre-payment and post-payment determinations. App., *infra*, 6a, 11a, 13a. Third, the Court premises its analysis on the so-called "logic of sample adjudication" referencing unrelated cases in other contexts which involved the use of statistical sampling. App. *infra*, 10a. The Court's review is akin to that of a legislative committee debating the merits of a proposal for legislation rather than that of a court attempting to interpret Congressional intent.

The sole governing authority with respect to the process that the Secretary must employ regarding coverage determination is set out in 42 U.S.C §1395ff(a). In pertinent part, it provides:

> The determination of whether an individual is entitled to benefits under Part A or Part B and the determination of the amount of benefits under Part A or Part B, and any other determination with respect to a claim for benefits under Part A or claim for benefits with respect to home health services shall be made by the Secretary in accordance with regulations prescribed by him.

42 U.S.C. §1395ff(a).

Notably, the Court of Appeals fails to reference the provision, in whole or in part, at any point in its ruling. It is difficult to understand how the Court could reach any conclusion without any analysis of this relevant portion of the Medicare Act.

The Court states that sample adjudication on initial review of payment claims would be inconsistent with the statute. App., *infra*, 6a. It further finds that the "process of reviewing initial payment claims requires particularized decisions," but then questions "whether the same rights to individualized factual determinations and an opportunity to challenge specific denials are at stake on post payment review." App., *infra*, 12a. Highlighting its distinction between pre-payment and post-payment determinations is the here-to-before unknown concept of a "reconsideration of approvals" in contrast to reconsideration of initial claim denials. App., *infra*, 13a. This entire system has been created by the court using language which appears nowhere in the Medicare Act and without reference to any relevant statute or regulation.

The essential problem the Court of Appeal has in its analysis is the failure to distinguish between the *standards* for Medicare benefits and the *process* for issuance of coverage determinations. The Court of Appeal continually confuses the

powers of the Secretary to deny payment for unnecessary care, 42 U.S.C. §1395y(a), recover overpayments, 42 U.S.C. §1395gg, or shift payment liability to beneficiaries and providers, 42 U.S.C. §1395pp, with the authority of the Secretary to implement a process to reach the substantive determinations. Petitioners have not disputed the power of the Secretary to recover overpayments. Instead, the controversy concerns the process of determinations that must be utilized by the Secretary to find that an overpayment has been made. Section 1395ff(a) unambiguously requires that the Secretary employ a process of individualized determinations for all substantive decisions.

The Secretary's claimed statutory authority for a method of sample adjudication for the process of claims determinations is set out in HCFA Ruling 86-1. The Court of Appeals summarily rejected this alleged authority finding that the provisions cited "deal with 'reasonable cost' rather than 'coverage determinations'." App., *infra,* 8a. The Secretary has cited 42 U.S.C. §1395g(a) which establishes the process for the Secretary to determine the amount of payment owing to a provider of services. Accordingly, the Secretary has recognized the distinction between statutory powers relative to substantive determinations and the process that must be followed in the issuance of the determination.

When the Court rejected the Secretary's claimed statutory authority for the process of coverage determination, it failed to fill the vacuum with an analysis of section 1395ff(a). However, Congress did not create a void in its statutory design.

Section 1395ff(a) represents a crucial component of an integrated system of Medicare coverage determinations which relies upon a unitary process of decisionmaking to coordinate the variety of substantive determinations delegated to the Secretary. For example, 42 U.S.C. §1395y(a)(1) excludes coverage of items and services which are not reasonable and necessary. Section 1395y(a)(1) itself, by its language or operation, does not establish the process for issuance of a determination relative to the standard of "reasonable and

necessary." That process is set out in section 1395ff(a) which governs all determinations with respect to benefit claims.

Similarly, 42 U.S.C. §1395gg authorizes the Secretary to recoup overpayments from beneficiaries and providers. No process for issuing the necessary determinations that benefits have been overpaid is set out in section 1395gg. Instead, the Secretary must find authority for the process of issuance of overpayment determination under section 1395ff(a). A finding that an overpayment has occurred presupposes the issuance of a determination that more than the correct payment has been made. If section 1395ff(a) did not exist, perhaps the Secretary could find some basis for implied authority. However, for section 1395ff(a) to serve any purpose, it must control the process of such determinations.

The integration of substantive rights and responsibilities within a single, unitary process of claim determinations is mmost evident relative to the rights of appeal from Medicare beneficiaries and providers. Those rights of appeal are set out in 42 U.S.C. §1395ff(b) which is triggered only through the issuance of a determination under section 1395ff(a). In the absence of a subsection (a) determination, there can be no appeal.[3] Certainly, allowing the Secretary to create a process for issuance of claim determinations independent of section 1395ff(a) would be illogical given the resultant loss of any statutory rights of appeal.

The Secretary has implemented section 42 U.S.C. §1395ff(a) in a manner which recognizes that all determinations, including matters related to coverage,

---

[3] Providers of services maintain a right of appeal separate from beneficiaries by virtue of 42 U.S.C. §1395pp(d) which accords providers the same rights that an individual has under section 1395ff(b). However, a pre-condition to these rights of appeal remains the issuance of a determination pursuant to the process under section 1395ff(a). for issuance of claim determinations independent of section 1395ff(a) would be illogical given the resultant loss of any statutory rights of appeal.

overpayments, and waiver of recovery or adjustment are subject to the same claim determination process. 42 CFR §405.704. No distinction is process is drawn between pre-payment and post-payment determinations. This process has existed since the inception of the Medicare program. It contains no reference to sample adjudication or any basis for the creation of such by way of implication.[4]

Harm abounds through the process of sample adjudication. The "chilling effect" created in an environment where any error of the Secretary is magnified exponentially and the appeal system that is available to correct errors is not expeditiously accessible is readily apparent. The most sensible recourse for providers is to narrow the margins for error by restricting access to care. While the restriction may eliminate non-covered care, it will also extend to services that would be covered under an accurate claim determination by the Secretary.

Petitioner Albuquerque Visiting Nurse Service best exemplifies the consequences for health care providers who do not respond to the threatened effect of sampling. Due to its inability to pay back alleged overpayments, it has ceased operation and is no longer an available health care resource in New Mexico.

The Medicare system itself is also at risk with sample adjudication. The recognition of the Medicare beneficiary as unique in terms of individual medical need is eliminated from the process of claims determinations. The individualized claim determination process which the Court of Appeals found required under the Medicare Act is rendered meaningless by post-payment claim adjudication. A pre-payment decision made on the basis of the patient's unique condition is eradicated by a post-payment determination based upon other standards applied the following day.

---

[4] The Court of Appeals reference to a sample adjudication policy from the *Medicare Intermediaries Manual*, App., *infra*, 20a , is misleading. This policy was issued subsequent to HCFA Ruling 86-1.

Each claim of every home health agency is subject to a individualized review prior to payment by Medicare. Sample adjudication re-reviews only a small portion of these same claims yet the accuracy of unidentified claims which had been individually reviewed is called into question. It strains logic to consider that a claim specifically reviewed and determined payable could be supplanted with a sample adjudication projection where no element of the claim is reviewed.

The Secretary has continually argued that this case does not concern beneficiaries. However, that short-sighted view ignores the partnership between the care provider and the patient in the health care spectrum and the intimate relationship between services and payment. The Court of Appeals' ruling has direct application to Medicare beneficiaries in that it provides authorization for the Secretary to create a separate post-payment claim determination process devoid of the Congressionally mandated notice under 42 U.S.C. §1395h(j)(1), the rights of appeal under 42 U.S.C. §1395ff(b), and the well-established principles of individualization. Providers of services also lose these protections which are integral elements of their partnership with patients. Sample adjudication is only one method of alternative claims processing that the Secretary can employ. While it might never be used directly against beneficiaries, the principle of law espoused by the Court of Appeals allows the Secretary to create any other method of post-payment claim adjudication process he believes reasonable which does not involve individualization of claims review.

Congress has made its choice through enactment of 42 U.S.C. §1395ff(a). The Secretary has usurped the power of Congress in creating an alternative system of claims processing. The future of the Medicare program and its goal to provide access to health care services is now in jeopardy.

III. *TheCourt of Appeals' Ruling Encourages Retroactive Rulemaking To Validate Past Conduct of An Agency.*

The mystical method of statutory construction employed by the Court of Appeals is reapplied in comparable form in its review of Petitioners' claim under the Administrative Procedures Act, 5 U.S.C. §553. At the heart of the determination of whether a rule is exempt from public notice and comment is whether the rule has the force and effect of law, i.e., it is binding on the decisionmaker. *Batterton v. Marshall*, 648 F.2d 694, 705 (D.C. Cir. 1980); *Gibson Wine Co. v. Snyder*, 194 F.2d 329 (D.C. Cir. 1952). However, the Court of Appeals found HCFA Ruling 86-1 to be "interpretive" despite the unambiguous language of the rule that it is binding, App., *infra,* 19a.

Similarly, the Court of Appeals found that HCFA Ruling 86-1 was "not the source of administrative authority," App., infra, 18a. This conclusion is in direct conflict with the actions of the Administrative Law Judge and the Appeals Council preceding this litigation where the claims of the Petitioners were rejected solely upon the basis of HCFA Ruling 86-1.

The Court's crucial error is its unsupported finding that the Secretary's policy of sample adjudication was longstanding. App., *infra,* 18a.[5] However, as late as 1986, the General Accounting Office indicated the Secretary has no sampling adjudication process for Medicare Part A. GAO Report No. HRD 87-9.

---

[5] The Court's reliance on *Mount Sinai Hospital* v. *Weinberger*, 517 F.2d 329, modified, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 US 935 (1976) is grossly misplaced. *Mount Sinai* Hospital did not involve the validity of sample adjudication and occurred prior to the enactment of legislation which afforded due process rights to providers of care, 42 U.S.C. §1395pp, as added October 30, 1972, P.L. 92-603, Title II, §213(a), 86 Stat. 1384.

The result of the Court's erroneous findings is the creation of a new standard in determining whether a rule is impermissibly retroactive under *Bowen v. Georgetown University Hospital*, 488 US 204; 208-213, 109 S.Ct. 468, 471-74; 102 K,Ed, 2d 493, 499-503 (1988). Under the Court of Appeals standard, a rule is valid if it is created after the completion of unauthorized actions which are the subject of the rule, but prior to the initiation of litigation in federal court to challenge the action.

If this Court allows the ruling to stand, administrative agencies will be authorized to retroactively validate administrative action under the claim that it is written policy which "merely explained and reaffirmed" longstanding practice. 931 F.2d at 923. The only instance of Medicare Part A claim sample adjudication prior to the matters at issue herein was in Mount Sinai Hospital where the relevance is extremely suspect. (See footnote 4).

An isolated, and likely irrelevant, prior use of a challenged practice does not constitute a longstanding policy. If such practice were so well-established, HCFA Ruling 86-1 would be unnecessary, certainly not to the extent to label it as binding within the Medicare program.

The Secretary's issuance of HCFA Ruling 86-1 is remarkably similar to Medicare' actions in *Georgetown University Hospital*. In both instances, the Secretary implemented a written rule which attempted to retroactively validate or authorize an action which was desired, but had not been authorized at the time the action occurred.

Allowing the Court of Appeals' ruling to stand will encourage administrative agencies to develop practices without written authority. If the agency escapes challenge in a single use of the practice, written rules would retroactively validate the practice when a challenge arises. By failing to commit its practice to a written rule prior to original use, the agency improves its chances that its intentions will avoid scrutiny. With such procedures, advance public notice and

opportunity to comment -- the essential purpose of the A.P.A. -- will be lost.

CONCLUSION

The questions presented to the Court in this Petition fit squarely within the considerations governing review or writ of certiorari as set forth in Rule 10 of the Revised Rules of the Supreme Court of the United States (1990). The standard of statutory construction employed by the Court of Appeals establishes a dangerous precedent which creates the opportunity for courts to disregard statutory language and to substitute a judicial ruling for legislative enactments and administrative rules.

The specific Medicare issues involved in sample adjudication also represent special and important questions of federal law which have significant impact on the operation of the primary health insurance program for this nation's elderly and disabled. Finally, the ruling dismantles the Administrative Procedures Act by permitted retroactive rulemaking under the guise of a claim that the rule merely memorializes the basis for the agencies' past conduct.

The ruling is at odds with well-established precedent of this Court. Moreover, the issues presented involve vital elements of the administration of Medicare. For these reasons, and those set out in detail above, the Petitioners respectfully request that this Court grant review.

Respectfully submitted,

William A. Dombi
Center for Health Care Law

Stanley M. Brand
Brand and Lowell

Attorneys

October 1991

APPENDIX A

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S.App.D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 22, 1991 Decided April 26, 1991

No. 90-5100

CHAVES COUNTY HOME HEALTH SERVICE, Inc., *et al.*

APPELLANTS

LOUIS W. SULLIVAN, M.D., SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Appeal from the United States District Court for the District of Columbia

(Civil Action No. 86-02691)

James C. Pyles, with whom *Barbara S. Woodall* was on the brief, for appellants.

Robert M. Loeb, Attorney, Department of Justice, with whom *Stuart M. Gerson*, Assistant Attorney General, *Jay B. Stephens*, United States Attorney, *Barbara C. Biddle*, Attorney, Department of Justice, and *Henry R. Goldberg*, Counsel, Department of Health and Human Services,

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

were on the brief, for appellee. *John C. Hoyle*, Attorney, Department of Justice, also entered an appearance for appellee.

Before: MIKVA, *Chief Judge*, SENTELLE, and HENDERSON, Circuit Judges.

Opinion for the Court filed by *Chief Judge* MIKVA.

MIKVA, *Chief Judge*: Several home health care providers appeal from a district court decision rejecting their challenges to procedures adopted by the Department of Health and Human Services ("HHS") for the recoupment of Medicare overpayments. Appellants contend that the Secretary of HHS improperly suspended the existing individual claims adjudication process under Part A of the Medicare Act and replaced it with a scheme based on statistical sampling to calculate amounts of overpayment. In granting summary judgment to HHS, the district court held that the statistical method violated neither the terms of the Act nor procedural due process, and that the Health Care Financing Administration ("HCFA") Ruling 86-1 (which purported to explain the Department's legal authority for engaging in sample adjudication) was neither retroactively applied nor subject to notice and comment rulemaking. *See Chaues County Home Health Services,Inc. v. Sullivan*, 732 F. Supp. 188 (D.D.C. 1990). We affirm the district court's decision.

I. BACKGROUND

Appellants are health care providers who receive Medicare payments from HHS for home health services they provide to eligible individuals. The Medicare program is divided into two main parts, one providing insurance for hospital and related post-hospital services (known as "Part A" *see* 42

U.S.C. §§ 1395c-1395i (1988 & 1990 Supp.)), and the other providing additional insurance for supplementary medical services ("Part B," *see* §§1395j-1395w). ("Part C," §§1395x-1395ccc, contains general provisions applicable to both Parts A and B.) The present dispute arises under Part A, which can be further divided into "coverage" determinations and "reasonable cost" determinations. *See Mount Sinai Hospital v. Weinberger*, 517 F.2d 329, *modified*, 522 F.2d 179 (5th Cir. 1975), cert. denied, 425 U.S. 935 (1976). Coverage determinations involve decisions about whether specific items or services are covered by Part A; reasonable cost determinations yield periodic interim payments to providers based on estimated costs incurred and subject to a year-end reconciliation. *See id.* at 335-36.

The present appeals concern only coverage determinations. The payment claims submitted by providers are initially processed by private entities under contract with the Department (called "fiscal intermediaries") on a case-by-case basis to determine (1) whether the amounts are for covered items or services provided to an eligible beneficiary, *see* §1395y(a)(1), and (2) whether, in case a service is not covered, HHS should waive this requirement. Waiver is routine so long as neither the beneficiary nor the provider knew or should have known that the items were not covered. *See* §1395pp(a). For purposes of the waiver determination, the Department presumes good faith by the beneficiary so long as he or she has not previously been notified that a service was not covered, *see* §1395pp(a)(2), and by the provider so long as fewer than 2.5% of its claims were disallowed in the previous quarter. *See* §1395pp(f)(1) & (4) (codifying the regulations in effect at the times relevant to these claims).

HCFA Ruling 86-1, *Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers* (Feb.

20, 1986), describes the Department's policy of allowing fiscal intermediaries to conduct post-payment sampling audits to recoup suspected overpayments. The Secretary concluded that sampling provides the only feasible means for protecting the Medicare Trust Fund in situations where a provider is suspected of overbilling and the number of claims involved is large. *See id.* at 10. HCFA Ruling 86-1 details the type of audit that is appropriate in such circumstances: the fiscal intermediary examines a randomly selected and statistically significant number of sample claims along with their supporting documentation to determine whether they involved noncovered services that the provider knew or should have known were not covered. These results are then extrapolated to the entire universe of claims from that provider for a given time period. The full amount of the provider's overpayment liability is calculated from the percentage of claims denied in the sample. *See id.* at 11. The provider is given the same opportunity to challenge the noncoverage and waiver determinations regarding sample claims as that provided on pre-payment review, and, in case of any incorrect determinations, the overcharge projection will be correspondingly reduced. The provider can also challenge the statistical validity of both the sample and the extrapolation.

In these cases, the Department decided to audit thousands of previously approved payment claims, allegedly after having received a tip that two of the appellants were overbilling, to determine whether there was a pattern of billing Medicare for non-covered services that the providers knew or should have known were not covered. The third appellant was targeted because its claims were so much higher than those of comparable providers. All the claims subject to post-payment review were initially approved, because the services were deemed covered or else waived on the premise that neither the provider nor the beneficiary had reason to know of non-coverage. Claims denied on post-payment review were ones involving non-covered services that HHS decided the

provider (but not the beneficiary) had reason to know were not covered.

The Department engaged in post-payment review of over 1000 claims submitted by and paid to Chaves County Home Health Service, Inc. ("Chaves"), over 2000 claims from Albuquerque Visiting Nurse Services, Inc. ("Albuquerque"), and over 10,000 claims from Bayonne Visiting Nurse Association, Inc. ("Bayonne"). The audit took representative samples of each group of claims (200 each from Chaves and Albuquerque, and 320 from Bayonne), determined that a certain portion of each sample group involved payment for non-covered services that the providers should have known were not covered, and then extrapolated that figure to all claims in assessing repayment liabilities (approximately $47,000 against Chaves, $138,000 against Albuquerque, and over $1.5 million against Bayonne). These figures were reduced after successful appeals regarding denied claims in the sample. The Department withheld payments of subsequent claims to offset the unpaid liabilities. It is about that offset that the providers complain.

II. ANALYSIS

A. Statutory Authority

The primary issue before us is whether Congress has allowed use of a sample auditing procedure for recoupment of overpayments to home health care providers. Nothing in the language or legislative history of the statute specifically authorizes sample audits on post-payment review of coverage determinations, but nothing expressly disallows it either. Appellants primarily rely on the individualized adjudication scheme for initial payment determinations and argue that a sample audit on post-payment review is incompatible with that scheme. By contrast, HHS emphasizes its general power to recoup overpayments and argues that this power

authorizes assessments for overpayments based on extrapolations from a sample audit. Although appellants repeatedly emphasize the small sample size used in these cases (averaging less than 10% of all claims), they never took issue with the statistical validity of the procedure in the proceedings below even though an opportunity for such challenge was made available. We accept the Secretary's reading of the statute as permissible.

According to appellants, nothing in the language of the statute or in its legislative history indicates that Congress authorized HHS to "suspend" individual coverage determinations and rights of appeal when such a procedure is deemed too burdensome. They argue that sample adjudication is incompatible with the statutory scheme requiring case-by-case review of payment claims to decide questions of coverage and waiver. Appellants do not take issue with sample auditing as such, but they assail the extrapolation of those results to the universe of all claims for recoupment purposes (hence the label "sample adjudication"). Appellants emphasize that extrapolation of a sample audit abrogates their right to appeal from specific denials, because they do not know which claims in a group were denied or the exact basis for the denials. The difficulty with their argument is that HHS has not, in fact, suspended individualized determinations and substituted sample adjudication on initial review of payment claims (a decision that would be inconsistent with the statute); instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling. We cannot find a statutory preclusion to such postpayment auditing nor to the method used to accomplish such objective.

In deciding the statutory question, we are of course guided by the principles set out in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). "If the intent of Congress is clear, that

is the end of the matter, .. . [but] if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843-44; see also *Sulliuan v. Everhart*, 110 S. Ct. 960, 964-66 (1990) (upholding as permissible the Secretary's construction of provisions of the Social Security Act as allowing a net calculation of over- and under-payments of benefits). Although at times appellants seem to be arguing that this is a "*Chevron* step one" case, they are hard pressed to show that Congress spoke to the specific question at issue here; both the statute and legislative history fail to say anything explicit for or against sample adjudication. Appellants ultimately must contend that the Department's interpretation of its authority is unreasonable and not entitled to deference under *Chevron's* second step.

Appellants claim that there is no statutory basis for the Secretary's asserted authority and that, even if there is, other provisions in the Act render unreasonable the Secretary's interpretation of the statute as allowing postpayment sampling audits. We address each contention in turn.

1. *Source of the Secretary's Authority*

The Department does not contend that its sample adjudication scheme for post-payment review of coverage determinations is based on explicit statutory authorization; it relies instead on its general (and uncontested) authority to recoup overpayments from providers. For example, §1395gg(b)(1) explicitly contemplates recoupment of overpayments to providers, declaring that where "more than the correct amount is paid under this subchapter to a provider of services ... and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider," an adjustment shall be made "by decreasing subsequent payments" to the

beneficiary. *See also* 42 C.F.R. § 405.370. Appellants contend that this case is not about whether HHS can recoup overpayments, but rather about how it decides that such overpayments have been made.

As discussed more fully below, sample adjudication has been used in previous instances involving post-payment review of coverage determinations" under Part A. In HCFA Ruling 86-1, the agency simply reiterated its belief that it had the latitude to employ sample audits on postpayment review to efficiently recoup overpayments for non-covered services.

Two courts reviewing post-payment sample adjudications of Part A coverage determinations failed to find any fundamental infirmity in the procedure. For example, in *Mount Sinai Hospital*, the court recounted that

> [a]llegations of wrongdoing by Mount Sinai in operation of the Medicare program were made in 1972. HEW subjected to review by a peer review committee of doctors a sample consisting of 710 patients from a single year. The statistical results of the committee's determinations of medically unnecessary hospital stays and ancillary services drawn from this sample were then applied to all years in question, producing a calculated, as opposed to actual, overpayment figure of $6.3 million.

517 F.2d at 333. Although it did not address the permissibility of sampling as such, the court held that the predecessor of HHS had a common law right of recoupment for overpayments involving services not covered under Part A. *See id.* at 343 ("Under these circumstances and in light of the construction we put on § 1395gg(b) . . ., we think it clear that recoupment has always been available to HEW under facts like those of the instant case."). *See also Daytona Beach General Hosp. v. Weinberger*, 435 F. Supp. 891, 892-93

(M.D. Fla. 1977). More recently, in *Mile High Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988), the court approved sample adjudication under Part B of Medicare.

Although HCFA Ruling 86-1 and the district court both cite Medicare sections that contemplate post-payment adjustments, these provisions deal with "reasonable cost" rather than "coverage" determinations. See 42 U.S.C. §§1395g(a) (authorizing "necessary adjustments on account of previously made overpayments or underpayments"), 1395u(a) (authorizing "such audits of the records of providers of services as may be necessary to assure that proper payments are made under" Part B), 1395x(v)(l)(A)(ii) (dictating that reasonable cost regulations shall "provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive"). Because they govern reasonable cost determinations, we do not read these provisions as explicit statutory authorization for sample adjudication on post-payment review of coverage determinations.

These provisions do, however, demonstrate that the Secretary generally has the duty and power to protect against overpayments to providers. We are not persuaded by appellants' suggestion that congressional silence in Part A should be construed as an intent to restrict postpayment audit procedures. As the court explained in *Mount Sinai Hospital*, "the specific authority for after-the-fact adjustments for payments subsequently found to be erroneous under HEW's reasonable cost regulations does not suggest that other after-the-fact repayments or adjustments were not contemplated." 517 F.2d at 345 (reversing district court's holding that the right to recoup coverage overpayments was abrogated by the comprehensive statutory scheme of the Medicare Act). In

fact, a 1981 amendment to the Act added a provision directing the Secretary to establish utilization guidelines concerning coverage of home health services and "provide for the implementation of such guidelines through a process of selective postpayment coverage review ...." 42 U.S.C. § 1395y(f).

In this case, the district court adopted the holding of another court that had upheld sample adjudication on the basis of these same provisions in the context of Medicare Part B. *See Mile High Therapy Centers*, 735 F. Supp. at 986 ("The above statutory citations give the Secretary considerable discretion and authority to maintain the integrity of the Medicare payment system."); *see also Bowen v. Georgetown Univ. Hosp.*, 109 S. Ct. 468, 472 (1988) (construing §1395x(v)(l)(A)(ii), a subsection governing reasonable cost determinations (quoted above)); *Wilson Clinic & Hosp., Inc. v. Blue Cross of South Carolina*, 494 F.2d 50, 52 (4th Cir. 1974) ("Reopenings are contemplated generally by the Act ... [which] impliedly, if not expressly, envisages the canvassing of all payments to a provider."). The court in *Mile High* concluded that "[t]he statistical sample method is one way of exercising this power" to preserve the integrity of the Medicare trust fund and did not exceed HCFA's statutory authority. *See* 735 F. Supp. at 986. Although Part B is somewhat different from Part A, there is no essential difference in their recoupment powers for coverage overpayments. *See Szekely v. Florida Medical Ass'n*, 517 F.2d 345, 348-49 (5th Cir. 1975), *cert. denied*, 425 U.S. 960 (1976). Furthermore, amendments added in 1986 extended Part A claims adjudication procedures to Part B claims as well. *See* §1395ff (amended by Pub. L. 99-509, § 9341, 100 Stat. 2037 (1986)). (Consequently, a contrary holding on the statutory question in this case could imperil sample adjudication under Part B.)

The logic of sample adjudication, accepted by courts that have approved the technique in other contexts, is that any

minor errors will tend to balance out in the end. As the district court correctly observed:

> The clear majority of those few courts having confronted statistical sampling in analogous contexts, while acknowledging its potential for unfairness in the abstract in particular cases, have nevertheless approved its use, primarily as a logistical imperative but also upon the hypothesis that any arbitrariness evens out in the long run.

Chaves, 732 F. Supp. at 189-90 (footnote omitted). Appellants point to decisions rejecting the Department's use of presumptions to make various determinations under the Social Security Act because these presumptions fail to satisfy the clear requirement for individualized determinations in certain provisions. But presumptions are not the functional equivalent of statistically derived patterns of over-billing by a particular provider. In other contexts and under other statutes, courts have routinely permitted the use of statistical sampling to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly. *See, e.g., Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) (Medicaid); *Michigan Dep't of Edu. v. United States Dep't of Edu.*, 875 F.2d 1196, 1204-06 (6th Cir. 1989) (vocational rehabilitation programs).

In *Illinois Physicians Union*, the court upheld the use of sampling audits to recoup Medicaid overpayments from participating physicians, squarely rejecting the contention that "any formula for sampling and extrapolation is improper per se," and holding that "extrapolation based on review of a relatively small sample is a valid audit technique in cases arising under the Social Security Act." 675 F.2d at 155. *See also State of Georgia v. Califano*, 446 F. Supp. 404, 409-10

(N.D. Ga. 1977) ("Audit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state [under Medicaid] would be a practical impossibility as well as unnecessary."). Similarly, in Michigan Department of Education the court upheld the government's use of a sample adjudication method to audit over 60,000 individual expenditure authorizations under the Rehabilitation Act. See 875 F.2d at 1205-06 ("[W]hen, as here, the state is given every opportunity to challenge each disallowance as well as the audit technique itself, it appears that the state has been treated as fairly as is practicable under the circumstances.").

HHS concedes, as it must, that these decisions do not settle the statutory question in this case, but the Department contends that these holdings support the reasonableness of the sampling procedure generally, and there is nothing explicit in this statute that would prohibit such a procedure here. Appellants maintain that even if the absence of explicit authorization in the statute is not fatal to the Secretary's procedure, other provisions in the Act render his interpretation unreasonable. As explained below, we agree with HHS that the statutory scheme of individualized review of claims on pre-payment review can be reconciled with a sample adjudication procedure on post-payment review. Such an interpretation is reasonable given the logistical imperatives recognized by courts in other comparable circumstances.

2. *Alleged Incompatibility with the Act*

The process of reviewing initial payment claims requires particularized decisions concerning (1) coverage (was an item or service medically necessary for this person?) and, if not covered, (2) waiver (which is unavailable when the parties knew or should have known that something was not covered). The beneficiary has a right of review for payment

denials based on either of these questions, and the statute specifies that a provider "shall have the same rights that an individual has" for review of Part A denials. *See* §1395pp(d). Much of appellants' statutory argument amounts to a collection of snippets from the Act and its history using the word "individual," though most of the time the term seems to act as a synonym for "person" or "beneficiary" rather than as an antonym for "group" or "class." The real question, however, relates not to the choice of particular words but more generally whether the same rights to individualized factual determinations and an opportunity to challenge specific denials are at stake on post-payment review.

Some of the provisions in the statute cited by appellants for their incompatibility argument, such as putting beneficiaries on notice that their claims were denied (for purposes of imputing knowledge for future waiver determinations), *see* §1395pp, or seeking repayment from a beneficiary when the provider is not available, *see* §1395gg, are simply not implicated in this case. Indeed, both of these provisions inure to the Department's benefit and presumably could be waived by HHS. In any event, all that the statute requires is notification in cases where the providers knew or should have known of non-coverage *and* HHS decides to indemnify the individual beneficiary for any payments they made to the provider. *See* §1395pp(b) ("[T]he Secretary shall notify such individual of the conditions under which indemnification is made ...."). These appeals do not involve indemnification (providers were paid directly for services they rendered tobeneficiaries), and nothing in the Act requires that a provider already deemed to have knowledge of non-coverage be given notice of such a non-coverage determination for purposes of imputing knowledge in the future.

A subsequent amendment to the Act added §1395h(j), which provides in pertinent part that, when a claim for home

health services is denied, the fiscal intermediary shall "furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial ...." Pub. L. 100-203, § 4032, 101 Stat. 133076 (1987) (applicable to claims received on or after January 1, 1988). Though apparently broader than the notice requirements of § 1395pp in effect at the time, the new provisions only cover initial claim denials, *see* §1395h(j)(1), or reconsiderations of such denials, *see* §1395h(j)(2), without ever mentioning reconsiderations of approvals. Furthermore, section 1395pp(a), which required notification of both the provider and beneficiary in cases where non-coverage was waived, only applies when neither party was already on notice and therefore would not be relevant in cases such as these where the provider is later deemed to have had the requisite knowledge of non-coverage.

Nor are the providers' rights to seek reimbursement from beneficiaries implicated in these cases. The legislative history accompanying §1395pp recognized that in cases where the beneficiary knew or should have known of non-coverage, "liability would remain with the beneficiary and the provider could ... exercise his rights under State law to collect for the services furnished ...." S. REP. No. 1230, 92d Cong., 2d Sess. 294 (1972). For purposes of the original claims approvals here, the beneficiaries were deemed to be without knowledge of any non-coverage. The revised waiver determinations on post-payment review only applied to the providers. *See* HCFA Ruling 86-1, at 8-9. Under these circumstances, a provider would have no right to seek reimbursement for subsequently denied claims from the beneficiary unless the provider could show that the beneficiary (including any outside the sample) was previously informed that he was receiving noncovered services. *See id.* Furthermore, even if the provider could show that the beneficiaries of payment claims denied without review also had the requisite knowledge (notwithstanding the provider's implicit representation that such knowledge was

lacking when the claim was initially submitted), providers are constrained in their ability to charge patients for services subsequently deemed to be non-covered. *See* §1395cc(a)(1)(B) (providers must agree not to seek reimbursement from patients for services that HHS decides are not covered more than three years after original notice of payment, and the Secretary may reduce this statute of limitations to one year if circumstances warrant).

Appellants also contend that sample adjudication vitiates their rights to appeal. Unlike the notice requirements discussed above, the statute makes no apparent distinction between pre-payment and post-payment review when setting out an individual's right to appeal an adverse determination. A beneficiary's right to appeal extends to "any determination" with which an individual is dissatisfied. *See* 42 U.S.C. §1395ff(b). As noted previously, §1395pp(d) accords providers the same rights as individuals. The issue, then, is whether the right to appeal initial claim denials is fully transferable to denials on postpayment review, or whether a right to dispute denials in the sample and challenge the statistical validity of the extrapolation suffices to protect the interests of providers. Appellants fill in this crucial gap in their position by relying on a supposed concession by HHS that, in appellants' words, a provider's "rights are the same whether the claim is being adjudicated at the time it is submitted or upon post-payment review." However, HHS made no such concession, noting only that its sample adjudication procedure afforded providers the same protections and right to challenge denials in the sample group, not that the rights were equally applicable to all post-payment denials. Nothing in the statute appears to require case-by-case review of all claims on post-payment review. At best, congressional intent on the matter is ambiguous.

The question is what "determination" was made in these cases that could be subject to appeal. As HCFA explained in its ruling, "[s]ampling only creates a presumption of validity

as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step." Ruling 86-1, at 11. A provider might first of all object to a coverage or waiver determination as to a claim in the sample, and HCFA's sample adjudication scheme permitted such challenges. In fact, the providers in these cases were able to successfully challenge many of the denied sample claims, thereby reducing their projected overpayment liability. Secondly, a provider may also take issue with the statistical validity of an extrapolation from the sample, and this right was also available in the proceedings below. Although they repeatedly emphasize that the sample sizes were too small, appellants failed to make any such objections to the statistical validity of the extrapolation in the proceedings below. Instead, the providers argued that the entire scheme is unauthorized because their right to appeal specific claim denials has been foreclosed.

Sample adjudication is not, however, a determination that some particular, though unidentified claims outside the sample should have been denied; instead, it is a monetized estimate of the scope of a provider's overcharges derived from a sample. To the extent that appellants were dissatisfied with *that* adverse determination, they were given an ample opportunity to challenge its basis. This is not to say that the providers were prohibited from raising challenges based on particular claims in the non-sample universe. For instance, as explained previously, a provider is permitted to identify individual beneficiaries of claims not in the sample who were on notice that the claims involved non-covered services and to then directly bill those beneficiaries. Furthermore, in an effort to challenge the accuracy of the extrapolation, a provider could separately present evidence of a different random sample from the universe of claims that yields a lower rate of denials or prove that the projection is not a true estimate of the rate of denials in the non-sample universe.

For instance, if a sampling projection estimated 100% denials in the non-sample universe, a provider could demonstrate that one or more of those unreviewed claims was proper.

Even when a provider is not able to invalidate the statistical validity of the sample audit, if the extrapolation has improperly invalidated any number of correct claims the provider could always appeal the determination by establishing the validity of all or a sufficient number of its actual claims to demonstrate that the HHS projection is factually impossible of correctness. Obviously, where thousands of claims are involved, this would impose a daunting burden on the provider, but the alternative urged by appellants imposes an equally daunting burden on the agency. It is not apparent to us that the regulatory scheme becomes invalid simply because it requires the protesting provider rather than the agency to bear the burden.

Appellants also claim that the Department's interpretation of the statute is not entitled to deference because it conflicts with HHS regulations,and policy statements. They contend that the regulations implementing Part A, *see* 42 C.F.R. §§ 405.701-.750 (1989), clearly require individual factual determinations and administrative review in making coverage denials. When initial determinations of non-coverage and no waiver are made on payment claims, the provider is entitled to written notice "stat[ing] in detail the basis for the determination." 42 C.F.R. § 405.702. At the request of an aggrieved party, initial payment denials can be reconsidered (§ 405.710), and providers are entitled to the same procedural rights on reconsideration, including a written statement (§ 405.716) and administrative review (§405.720). Again, to the extent that the regulations and other agency pronouncements reiterate the requirement for case-by-case review at the initial payment stage, they do not address the question of post-payment sample audits for recouping overpayments.

HHS emphasizes that sample adjudication is a longstanding practice, utilized at least since 1972. Indeed, internal manuals clearly contemplate just such a procedure. For example, the *Medicare Intermediaries Manual*, brought to the district court's attention by the plaintiffs, provides that

> [tlhe decision to conduct a sample study of a provider's claims constitutes a reopening of all determinations .... Send a notice to the provider as soon as possible explaining: the reason for the study (*e.g.*, possible over-utilization of services); the period to which the results will apply; the sampling procedure, including the method used to select the sample and a statement that the sample findings will be projected to the entire population of claims.

Medicare Intermediaries Manual, § 3799.5. Furthermore, the regulations governing the collection and compromise of claims for over-payments against providers appear to draw a distinction between pre-payment and postpayment review in defining the scope of the right to appeal. *See* 42 C.F.R. § 405.374(j) ("Any action taken by HCFA under this section regarding the compromise of an overpayment claim ... is not an initial determination for purposes of the appeal procedures" under, *inter alia*, 42 C.F.R § § 405.702-.730.) . Appellants are thus unable to demonstrate that the sample adjudication procedure used in these cases was incompatible with either the statute or Department regulations. Thus, we cannot say that the Secretary's interpretation of his authority under the Act is unreasonable.

B. *Procedural Due Process*

Appellants contend that they enjoy a clear property interest in retaining previously made payments for services rendered and are therefore entitled to the protections of due process.

To sustain such a contention they have a very difficult burden of persuasion in light of the three-factor analysis adopted in *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). Absent an explicit provision in the statute that requires individualized claims adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens; in light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates. *See Illinois Physicians Union*, 675 F.2d at 157 ("[I]n view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available."). It should be remembered that appellants failed in these cases to timely and specifically challenge the statistical validity of the sampling procedure as applied to them. HHS emphasizes that providers have no legitimate expectation of retaining payments for services they knew or should have known were not covered, that subjecting the audit to notice and hearing minimizes the risk of error, and that the cost of case-by-case review would exceed the amounts of overpayment. We can find no general constitutional defect with sample adjudication.

C. *Irregularities in Adoption of HCFA Ruling 86-1*

1. *Retroactive effect*

Appellants urge that their challenges before the agency to the sample auditing procedure were rejected on the strength of HCFA Ruling 86-1 even though that ruling was issued after their overpayment assessments were made. If Ruling 86-1 changed HHS procedures, then its use here indeed would be impermissibly retroactive. *See Bowen v. Georgetown Univ. Hosp.*, 109 S. Ct. 468, 471-74 (1988). However, the Ruling was not the source of administrative authority in these cases but merely explained and reaffirmed the Department's

long-standing and well-established practice of conducting sample audits. While the past frequency of such audits is unclear, the practice appears to have been in use as early as 1972. *See Mount Sinai Hosp.*, 517 F.2d at 333; *Daytona Beach General Hosp.*, 435 F. Supp. at 892-93. The audits at issue in *Mile High Therapy Centers*, 735 F. Supp. at 985, were undertaken in the early 1980s, and the sample audits in the cases before us on appeal also predated HCFA Ruling 86-1. Moreover, sample auditing is referenced in internal agency manuals. *See Medicare Intermediaries Manual*, § 3799.5 (quoted above); *Medicare Carrier's Manual* § 7150 (discussed in *Mile High*, 735 F. Supp. at 985-86). In light of this evidence that sample adjudication represents a long-standing HHS procedure, we reject appellants' retroactivity objection.

2. *Compliance with APA Rulemaking Procedures*

Appellants finally contend that HCFA Ruling 86-1 was adopted without the notice and comment procedures required by the Administrative Procedure Act (APA). *See* 5 U.S.C. § 553 (1988). The sole question is whether Ruling 86-1 is excepted from the APA requirements as an interpretive rule. *See* § 553(b)(A); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-47 (D.C. Cir. 1987). Appellants argue that HCFA Ruling 86-1 is a legislative rule, and not just an advisory statement, because it is binding both by its own terms and as used by the Department in the proceedings below. The Department responds that it has been performing sample audits for nearly two decades and that HCFA Ruling 86-1 simply states what the agency thinks it can do under the statute and reminds parties of their existing duties. *See Mile High*, 735 F. Supp. at 985-86 (holding that HCFA Ruling 86-1 is an interpretive rule not subject to notice and comment rulemaking requirements); *cf. McCown v. HHS*, 796 F.2d 151, 157 (6th Cir. 1986) (policy statement concerning offset policies for social security disability benefits was

interpretive), *cert. denied,* 479 U.S. 1037 (1987). The dispute, therefore, boils down to the previously-resolved question of whether sample adjudication for Part A overpayments was a longstanding practice or a brand new scheme ushered in by HCFA Ruling 86-1. As explained above, we agree that it was the former.

III. CONCLUSION

Appellants' remaining challenges to the proceedings below are equally without merit. The statutory question is complicated, but this much is clear: neither the plain language nor the legislative history discusses sample adjudication. Appellants' claim that HHS is proposing an unreasonable interpretation of its authority under the statute is close, but not strong enough to trump the deference we must accord agency interpretations of an ambiguous governing statute under *Chevron.* Sample adjudication represents a judicially approved procedure that can be reconciled with existing Medicare requirements for case-by-case consideration on pre-payment review of claims. The district court's order granting summary judgment to the Secretary of HHS is

Affirmed.

APPENDIX B

UNITED STATES COURT OF APPEALS

For the District of Columbia Circuit

No. 90-5100 **September Term**, 1990
USDC Civ. No. 86-2691

Chaves County Home Health Service Inc., et al.,
Appellants

FILED: JUL 26 1991
CONSTANCE L. DUPRE
CLERK

v.

Louis W. Sullivan, M.D., Secretary of the Department of Health and Human Services, et al.,
Appellees

Before: MIKVA, Chief Judge; SENTELLE and HENDERSON, Circuit Judges

ORDER

Upon consideration of appellants' Petition for Rehearing and of the response thereto, it is

ORDERED, by the Court, that the petition is denied.

Per Curiam:
FOR THE COURT:
CONSTANCE L. DUPRE, CLERK
By: Robert A. Bonner,
Deputy Clerk

APPENDIX C

SECTION 1815(a), 1842(a), and 1861(v)(1)(A)(ii) (42 U.S.C. 1395g(a), 1395u(a), and 1395x(v)(1)(A)(ii)). -- HOSPITAL INSURANCE AND SUPPLEMENTARY MEDICAL INSURANCE--USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

HCFAR-86-1

HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

The provider billed and was paid by Medicare for services to beneficiaries from September 1982 through July 1985. As a result of a subsequent audit of the provider's Medicare claims, the intermediary discovered a large number of bills for medically unnecessary services. The intermediary also determined that the provider knew or should have known that the services were not covered and, therefore, was not entitled to have payment made to it for the services.

The intermediary considered conducting a case-by-case review in order to determine the amount the provider had been overpaid for the services. This would have entailed an examination of all of the provider's beneficiary records for the period in question in order to identify those beneficiaries who had received unnecessary services. It also would have been necessary to tabulate the total amount that Medicare had paid the provider for each beneficiary. The intermediary decided that this method of determining the amount of the overpayment was not administratively feasible, given the volume of records involved and the cost

of retrieving and reviewing all the beneficiary records for the period in question. The cost of identifying and calculating each individual overpayment itself would constitute a substantial portion of the amount the intermediary might reasonably be expected to recover. Further, the allocation of sufficient staff to reexamine all individual claims for the period in question would interfere with current claims processing activities to an unacceptable degree.

The intermediary notified the provider that, because of the volume of records and the costs of retrieving and reviewing all records for the period as discussed above, it intended to project the overpayment by reviewing a statistically valid sample of beneficiary records and that if it were determined that the provider had been overpaid for the sample cases, it would project the results (again using statistically valid methods) to the entire population of cases from which the sample had been drawn. This would result in a statistically accurate estimate of the total amount the provider had been overpaid for services to these beneficiaries.

The provider objected to the intermediary's use of sampling to project the overpayment on the following grounds:

There is no legal authority in the Medicare statute or regulations for HCFA or its intermediaries to determine overpayments by projecting the findings of a sample of specific claims onto a universe of unspecified beneficiaries and claims.

Section 1879 of the Social Security Act, 42 U.S.C. 1395pp, contemplates that medical necessity and custodial care coverage determinations will be made only by means of a case-by-case review.

When sampling is used, providers are not able to bill individual beneficiaries not in the sample group for the services determined to be noncovered.

Use of a sampling procedure violates the rights of providers to appeal adverse determinations.

The use of sampling and extrapolation to determine overpayments deprives the provider of due process. (The succeeding presentation of our decision and supporting facts is applicable also to the use of sampling to project overpayments to suppliers (including physicians) whose claims are processed by Medicare carriers when 100 percent readjudication would be excessively costly or impractical.)

The Supreme Court has long recognized that the Federal Government possesses an inherent right to recover monies illegally or erroneously paid out. United States v. Carr , 132 U. S. 644, 650 (1890); Wisconsin Cent. R. R. v. United States, 164 U.S. 190, 212 (1986). This right exists independent of statute. See United States v. Wurts , 303 U.S. 414, 416 (1938); Grand Trunk W. Ry. v. United States, 252 U.S. 112, 121 (1920). The Government may enforce its right of recoupment by reasonable means, and it may exercise that right without resorting to litigation by offsetting the amount against sums otherwise due. United States v. Munsey Trust Co., 332 U.S. 234, 239-240 (1947). Offsets against current or subsequent obligations may be used to prevent a recipient of Federal funds from retaining monies that are later found to have been unauthorized by the terms and conditions under which they were received. Wisconsin Cent. R.R. v. United States, supra, 164 U.S. at 211-212.

The Government's common law right of recoupment, and its corollary power of recovery by offset, are based on strong considerations of public policy. All funds at the disposal of the Government belong to the public. As custodian of these funds, a Federal agency has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. Accordingly, if the public's money has been expended in a manner not authorized by statute, the agency's obligation requires it to take administrative actions necessary to prevent an unjust

enrichment by the recipient at the expense of the Federal treasury. See United States v. Wurts, supra, 303 U.S. at 415-416; Grant Trunk W. Ry. v. United States, supra, 252 U.S. 120-121.

The common law right to recover Federal funds has been specifically recognized as being fully applicable to the Medicare program. Mt. Sinai Hospital v. Weinberger, 517 F.2d 329 (5th Cir. 1975); Wilson Clinic and Hospital, Inc. v. Blue Cross, 494 F.2d 50 (4th Cir. 1974). Moreover, the courts have also recognized that extrapolation based on a sample is a valid audit technique in cases arising under the Social Security Act. Illinois Physician Union v. Miller , 675 F.2d 151 (7th Cir. 1982); State of Georgia v. Califano, 446 F.Supp. 404 (N.D. Ga. 1977); New Jersey Welfare Rights Organization v. Cahill , 349 F.Supp. 501 (D.N.J. 1972); Rosado v. Wyman , 322 F.Supp. 1173 (E.D. N.Y. 1970), aff'd 402 U.S. 991 (1971). In view of the enormous logistical problems in determining massive overpayments in social welfare programs, sampling is the only feasible method available. State of Georgia v. Califano, supra; Illinois Physicians Union v. Miller, supra.

Congress has affirmed the Government's right to recover Medicare Trust Funds by reasonable means from those who have no right to retain them. Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes "necessary adjustments on account of previously made overpayments or underpayments" under Medicare Part A. Similarly, as to Part B of Medicare, section 1842(a), 42 U.S.C. 1395u(a), provides that carriers make determinations as to the amount of payments to be made to providers of services and other persons, and authorizes such audits of the records as may be necessary to assure that proper payments are made. In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the "making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate

reimbursement produced by the methods of determining costs proves to be either inadequate or excessive." These statutory requirements, in effect, would be abrogated if sampling were not available to determine Medicare overpayments. The imposition of such a result would be inconsistent with the settled principle that, when Congress creates a statutory right, the existence of appropriate remedies to enforce that right will be presumed in the absence of a clar indication of a contrary congressional intent. Texas & N.O.R.R. v. Brotherhood of Railway & Steamship Clerks, 281 U.S. 548, 569-570 (1939); Sullivan v. Little Hunting Park, Inc., 396 U.S. 229, 239 (1969).

Since HCFA's contractors process vast numbers of Medicare claims (for example, in fiscal year 1985, intermediaries received over 59.5 million Medicare claims and carriers received over 270.8 million Medicare claims), an interpretation that title XVIII of the Act mandates that a 100 percent review of cases be conducted before HCFA or its contractors can determine that providers or suppliers have been overpaid would make it virtually impossible for HCFA to implement these statutory provisions in many cases. A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, HCFA must adopt realistic and practical auditing procedures. The alternative is to conclude that the intent of Congress was that, if case-by-case overpayment determinations are not administratively feasible, the Medicare Trust Funds must forego restitution of funds improperly obtained by providers and suppliers. We do not believe that was Congress' intent.

We also do not believe that the statutory provisions limiting provider or beneficiary liability preclude the use of sampling. In instances where Medicare coverage is denied because of items or services furnished are not "medically necessary" or constitute "custodial" care, section 1879 of the Act, U.S.C. 1395pp (42 CFR 405.330), authorizes

a limitation of the beneficiary's liability when the beneficiary did not know, and could not reasonably be expected to have known, that the items or services were not "medically necessary" or that they constituted "custodial" care. The Medicare program will make payments to the provider when both the beneficiary and the provider were without the requisite knowledge. When the beneficiary did not have such knowledge, but the provider did, liability for the denied services rests with the provider and the beneficiary's liability is waived. The beneficiary will be indemnified by the Medicare program if he or she has already paid the provider. See 42 U.S.C. 1395pp. Liability will rest with the beneficiary only when he or she knew or could have been expected to know that the items or services furnished were not "medically necessary" or were "custodial" in nature.

The use of sampling to determine overpayments for medically unnecessary services or custodial care does not deprive a provider of its right to bill those beneficiaries who knew or should have known that they were receiving these services. Under the governing regulation, 42 CFR 405.334, a beneficiary is presumed not to have had such knowledge unless he or she was notified in writing by the provider, the intermediary, or the Peer Review Organization (PRO). For example, when a beneficiary who is receiving a course of treatment has received a previous denial notice stating that similar items or services were not covered, the previous denial notice would constitute evidence that the beneficiary did or should have had knowledge of noncoverage. See 42 CFR 405.334 for examples of acceptable written notice to the beneficiary. The operation of this provision effectively serves to resolve most limitation of liability questions in the beneficiary's favor. However, a provider that wishes to bill individual beneficiaries not included in the sample can identify whose individuals who were previously informed that they were

receiving noncovered services by inquiring of the intermediary or PRO as to whether it sent a notice to the individual. (The provider presumably did not give notice to the beneficiary that the services were not covered because, if it had, it is unlikely that it would have billed Medicare for the services.)

Even if we assume that a provider is effectively precluded from billing a beneficiary in certain cases, this assumption would not bar the Government from its fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. As between the provider and the Government, strong considerations of public policy favor recovery. On the other hand, the provider had the responsibility to know and should have known that the services furnished were not medically necessary. Moreover, as the United States Court of Appeals for the Fifth Circuit recognized in Mt. Sinai Hospital of Greater Miami v. Weinberger, 517 F.2d 329 (5th Cir. 1976), the provider assumes substantial responsibility for overpayments.

. . . [the hospital] is not a neutral, innocent party in this three-way transaction between HEW, Medicare beneficiary and Medicare provider. The decision to provide a service is made by the individual attending physician, who is far better informed on both the medial issue and the scope of Medicare coverage than is the patient-beneficiary. The physician is either an employee of the hospital or a doctor with staff privileges. Whatever else the granting of staff privileges may connote, it is clear to us that it involves a delegation by the hospital of authority to make decisions on utilization of its facilities. 534 F.2d at 338.

In reimbursing providers, HCFA has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act. Mixed into this balance is the volume of claims which must be

reviewed. Considering the volume of claims (as cited earlier to be over 330.3 million for fiscal year 1985), it is virtually impossible to examine each bill submitted by a provider or supplier in sufficient detail to assure before payment in every case that only medically necessary services have been provided. Therefore, as a practical matter, HCFA and its contractors must

depend on the provider to submit claims for services that are covered by the Act. In most cases, this reliance is justified. However, if HCFA or its contractors later have reason to make an indepth and careful review of claims for services which had been previously paid and discover that medically unnecessary services have been provided, a provider cannot cry "foul" when these payments (to which they were never legally entitled) are recovered.

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

The provisions of the statutes and regulations provide a constitutionally sufficient means by which the provider may challenge an overpayment determination. In cases of denials made through sampling which are based on

medical necessity or custodial care, section 1879 of the Act, 42 U.S.C. 1395pp, permits the provider to assert the same appeal rights that an individual has under the statute when the individual does not exercise his rights to appeal. Under Part A, these rights include an opportunity for reconsideration (42 CFR 405.710-504.716), an oral evidentiary hearing by an administrative law judge (42 CFR 405.720-405.722), Appeals Council Review (42 CFR 405.701(c) and 405.724), and finally judicial review if the amount in controversy is $1,000 or more (42 CFR 405.730; 42 U.S.C. 1395ff(b)(2)). In cases which do not involve medical necessity or custodial care, 42 CFR 405.370, et seq. sets out the applicable procedures through which current payments may be suspended (offset) to recover an overpayment under the Medicare program. Under 42 CFR 405.371, a provider is given notice as to the basis for the overpayment and an opportunity to respond before an intermediary may suspend current Medicare reimbursement. 42 CFR 405.372, in conjunction with 42 CFR 405.370(b), forestalls any suspension pending consideration of any statement by the provider in opposition to the notice of suspension. Finally, if it is determined that a suspension should go into effect, written notice of the determined will be sent to the provider or other supplier. The notice will contain specific findings on the conditions upon which the suspension was based and an explanatory statement for the final decision. Thus, the administrative scheme provides sufficient means for a provider to challenge overpayment determinations that are made on the basis of sampling.

Under Part B, suppliers who accept assignment may request a Medicare carrier to review a payment determination with which the supplier disagrees (42 CFR 405.807). If the supplier is dissatisfied with the carrier's review determination, the supplier may request a hearing before a carrier hearing officer if the amount in controversy is $100 or more (42 CFR 405.820). There are no further appeals

available under Part B. In U.S. v. Erika, Inc., 456 U.S. 201 (1982), the Supreme Court ruled unanimously that, under current law, the Part B hearing is rightfully the final step in the Part B appeals process.

In summary, the use of sampling is a reasonable and cost effective method of projecting overpayments under Medicare. It is not unfair to a provider or supplier to hold it accountable for the receipt of Medicare funds to which it is not entitled under the statute. To the contrary, allowing a provider or supplier improperly to retain large sums of program funds would be unfair to the intended beneficiaries of Medicare and to the taxpayers who contribute to the trust funds. As the Supreme Court held in Richardson v. Perales, 402 U.S. 389 (1971), the system must not only be fair, but it must work.

Accordingly, it is held that the use of statistical sampling to project an overpayment is consistent with the Government's common law right to recover repayments, the Medicare statute, and the Department's regulations, and does not deny a provider or supplier due process. Neither the statute nor regulations require that a case-by-case review be conducted in order to determine that a provider or supplier has been overpaid and to determine the amount of overpayment.

DATED: 2/20/86

Henry R. Desmarais

Acting Administrator, Health Care
Financing Administration